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EP 0597341 A1 WO 94/01160 A1 US 4775371 A
US 4385635 A

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(54) Abstract Title

Medico-surgical tube

(57) A medico-surgical tube 1, eg a catheter, is formed with an inner layer 11 and an outer layer 12, at least part of the inner layer being removed from one end 13 of the tube, such that the stiffness of the tube is reduced at this end. To achieve a soft tip 2 at the end of the tube, the inner layer is made of a more rigid material than the outer layer. Preferably, the inner layer is removed from the tip by machining (see figures 4-6), which is subsequently end-formed closed and a side opening 3 cut into it.

Fig.2.

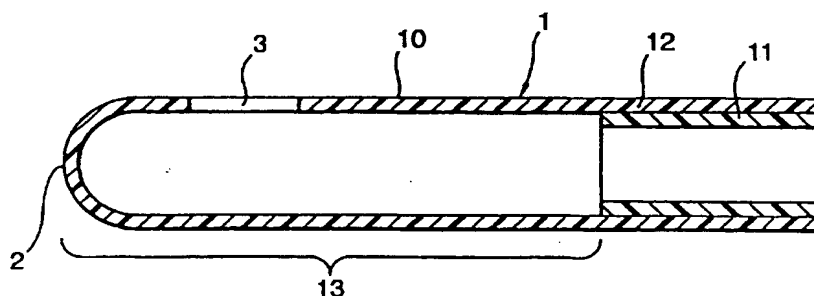


Fig.1.

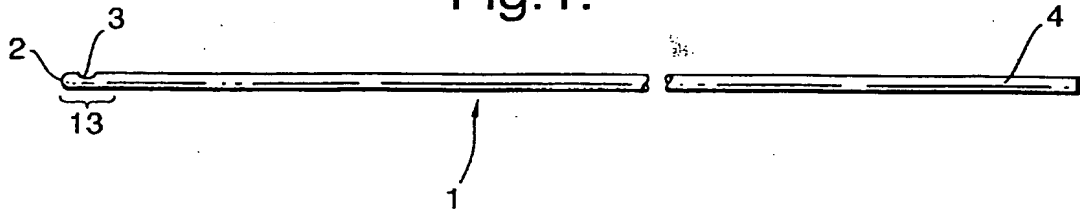


Fig.2.

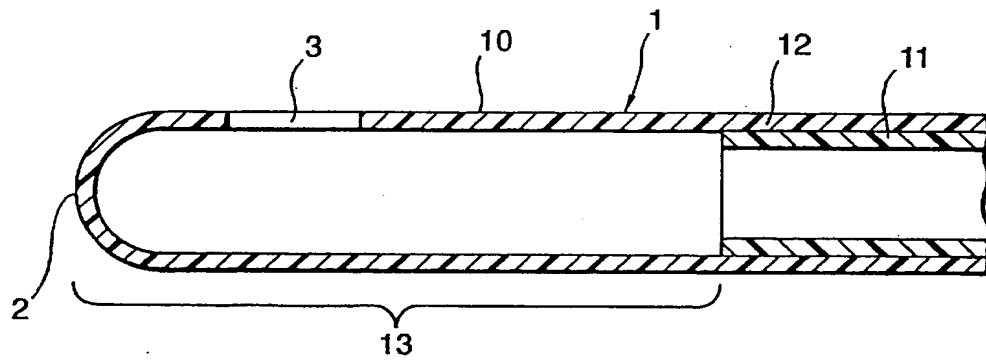


Fig.3.

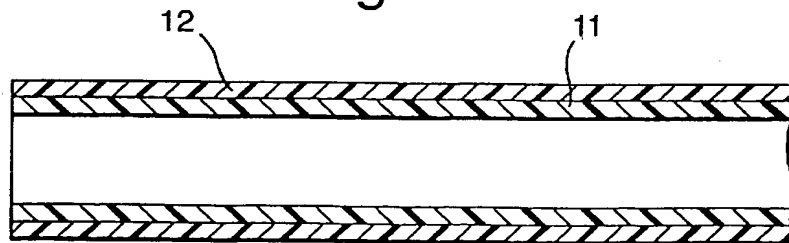


Fig.4.

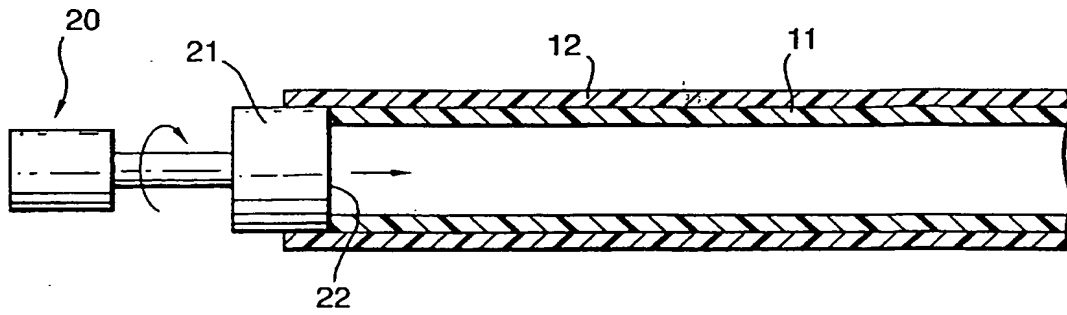


Fig.5.

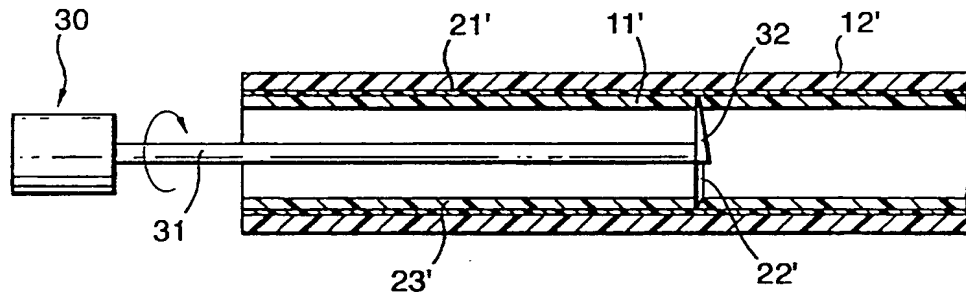
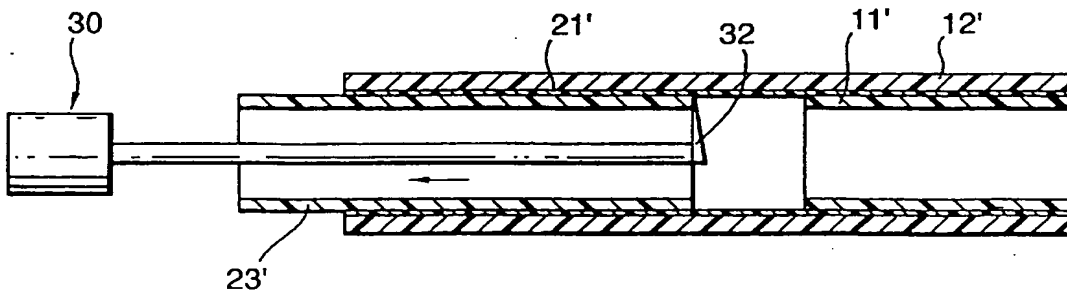


Fig.6.



MEDICO-SURGICAL TUBES AND METHODS OF MANUFACTURE

This invention relates to medico-surgical tubes and methods of manufacture.

The invention is more particularly concerned with tubes with a soft tip, and with methods of manufacture of such tubes.

It is often desirable for medico-surgical tubes, or catheters, to have a soft tip, so as to reduce trauma caused when the tip contacts patient tissue. In epidural catheters, a soft tip reduces the risk that the catheter will damage the dura. Various arrangements have been proposed for providing a soft tip, such as by attaching or moulding onto the shaft of the catheter a separate component of a softer material. Such an arrangement is not entirely satisfactory because a separate assembly operation is needed to form the tip, leading to increased manufacturing expense. Also, there is always some risk that a separate component might become detached from the body of the catheter. Other arrangements in which the rear part of the catheter is reinforced can also be difficult to make by automated assembly, thereby making the catheter relatively expensive. GB9906349 describes a catheter with a soft tip formed by extruding a tube with an inner layer of stiffer material, which is periodically interrupted to provide more flexible regions. In WO 94/01160 there is described an epidural catheter where an inner tube is preformed and then an outer tube is provided around it extending beyond the inner tube to form a less stiff region.

It is an object of the present invention to provide an alternative medico-surgical tube and method of manufacture of a such a tube.

According to one aspect of the present invention there is provided a medico-surgical tube having an inner layer and an outer layer, a part at least of the inner layer being removed from one end of tube such as to reduce the stiffness of the tube at the one end.

The tube may have an interlayer, such as of polyethylene, between the inner and outer layers preventing bonding between the inner and outer layers and enabling the part of the inner layer to be pulled from the one end of the tube. The tube is preferably closed at the one end and has a side opening towards the one end. The inner layer is preferably stiffer than the outer layer.

According to another aspect of the present invention there is provided a method of making a medico-surgical tube including the steps of forming a tubular member with an inner and outer layer, and subsequently removing a part at least of the inner layer along a region at one end of the tube such as to reduce the stiffness of the tube along the region.

The part of the inner layer may be removed by machining away the part of the inner layer along the region. The part of the inner layer may be machined away using a machine having a rotating milling head with a milling surface on an end face. Alternatively, the part of the inner layer may be removed by cutting away the part from the remainder of the inner layer and pulling it out of the tube. The part of the inner layer may be cut away using a machine having a rotating spindle carrying a radially-extending knife blade. Preferably the tube has an interlayer, such as of polyethylene, between the inner and outer layers preventing bonding between the inner and outer layers. The inner layer may be of a stiffer material than

the outer layer. The outer layer is preferably end formed after removal of the part of the inner layer to close the one end of the tube, a side opening being formed in the tube towards the one end.

According to a further aspect of the present invention there is provided a medico-surgical tube made by a method according to the above other aspect of the invention.

According to a fourth aspect of the present invention there is provided a machine for use in the method according to the above other aspect of the invention.

An epidural catheter and a method of making an epidural catheter according to the present invention, will now be described, by way of example, with reference to the accompanying drawings, in which:

- | | |
|-----------------|--|
| Figure 1 | is a side elevation view of the catheter; |
| Figure 2 | is an enlarged cross-sectional side elevation view of the patient end of the catheter; |
| Figures 3 and 4 | are enlarged cross-sectional side elevation views showing stages in a method of manufacture of the catheter; and |
| Figures 5 and 6 | are an enlarged cross-sectional side elevation views showing stages in an alternative method of manufacture of the catheter. |

With reference first to Figure 1, the catheter 1 is about 75-100cm long with a rounded tip at its patient end 2 and a side opening 3. The machine end 4 of the catheter 1 is open and cut square for attachment to a conventional epidural connector, not shown.

Referring now also to Figure 2, the wall 10 of the catheter 1 is extruded from a thermoplastics material. The wall 10 has an inner layer 11 of nylon and an outer layer 12 of polyurethane, the nylon being stiffer than the polyurethane. Alternatively, both layers 11 and 12 may be of the same polymer, such as PVC, but with differing amounts of plasticizer so that the inner layer is stiffer. Towards the patient end 2 of the catheter 1, there is a region 13 about 2cm long where the inner layer 11 has been removed, thereby making this more flexible than the remainder of the catheter 1, and making the tip 2 relatively soft. This reduces the risk of damage to the dura and enables the forward end of the catheter 1 to bend more easily to conform to the shape of the epidural space with a reduced risk of kinking. Because the inner layer 11 is stiffer than the outer layer 12, it can be relatively thin and still provide sufficient rigidity to the main part of the catheter. This ensures that the internal diameter of the catheter 1 is kept as large as possible.

The inner layer 11 can be removed from the tip of the catheter in various ways, such as illustrated in Figures 3 and 4. Figure 3 shows tubing as it emerges from a co-extruder, having an inner layer 11 extending along its entire length. The tubing is then cut into lengths and the inner layer 11 is subsequently removed by machining it away, such as with a milling machine 20 of the kind shown in Figure 4. The machine 20 has a milling head 21 of cylindrical shape with a milling surface formed on its front face 22. The diameter of the head

21 is equal to the external diameter of the inner layer 11. The milling head 21 is rotated about its axis and is pushed axially into the tubing so as to cut away the inner layer 11 and to leave the outer layer 12. The head 21 is pushed in until the inner layer 11 has been machined away along the region 13. The machine 20 is then removed, the swarf is flushed from the tube and the tube is end formed in a conventional manner, such as by means of a heated mould, to close and round the end. The side eye 3 can be formed at any time.

It is not essential to remove the entire thickness of the inner layer 11 since some reduction in stiffness can be achieved by removing only an inner part of the thickness of the layer.

An alternative way of removing the inner layer 11' is shown in Figures 5 and 6. In this method, the tubing is extruded with an additional interlayer 21' of polyethylene between the outer layer 12' and the inner layer 11', which serves to prevent bonding between the inner and outer layers. After cutting into appropriate lengths, a cutting machine 30 is used to remove the inner layer 11'. The cutting machine 30 has a rotatable spindle 31 carrying a radially-extending knife blade 32 at one end. The blade 32 is inserted, while stationary, into the end of the tube to a depth equal to that of the region 13 from which the inner layer 11' is to be removed. The machine 30 then rotates and centres the spindle 31 within the tube. The length of the knife blade 32 is selected so that its tip traces a circle of diameter equal to the external diameter of the inner layer 11' and thereby produces a circular cut 22' through the inner layer without penetrating the outer layer 12'. The spindle 31 and blade 32 are then stopped rotating and are pulled out of the tube, as shown in Figure 6, with the blade pulling out the section 23' of the inner layer 11' forwardly of the cut 22', which has been separated

from the remainder of the inner layer. The interlayer 21' ensures that this section 23' of the inner layer 11' can be slid relative to the outer layer 12'. It is not important whether the knife blade 32 cuts through the interlayer 21' and whether this is removed with the section 23' of the inner layer 11', or whether it remains within the outer layer 12'. Alternatively, a separate tool could be used to remove the section 23'. The end of the tube is then formed in the manner described above. This arrangement has the advantage that less or no swarf is produced.

The method of making the catheter 1 enables a soft patient end tip 2 to be provided without the need for subsequent assembly operations.

It will be appreciated that the invention is not confined to epidural catheters but could be used to provide a tip of reduced stiffness to other tubes such as endotracheal tubes. The catheter could be reinforced such as by incorporating a helical reinforcing element, or a braid into the outer layer. A lumen could be formed along the outer layer for various conventional purposes. The tip could be open or closed.

CLAIMS

1. A medico-surgical tube having an inner layer and an outer layer, wherein a part at least of the inner layer is removed from one end of tube such as to reduce the stiffness of the tube at the one end.
2. A medico-surgical tube according to Claim 1 having an interlayer between the inner and outer layers preventing bonding between the inner and outer layers and enabling the part of the inner layer to be pulled from the one end of the tube.
3. A medico-surgical tube according to Claim 2, wherein the interlayer is of polyethylene.
4. A medico-surgical tube according to any one of the preceding claims, wherein the tube is closed at the one end and has a side opening towards the one end.
5. A medico-surgical tube according to any one of the preceding claims, wherein the inner layer is of a stiffer material than the outer layer.
6. A method of making a medico-surgical tube including the steps of forming a tubular member with an inner and outer layer, and subsequently removing a part at least of the inner layer along a region at one end of the tube such as to reduce the stiffness of the tube along the region.

7. A method according to Claim 6, wherein the part of the inner layer is removed by machining away the part of the inner layer along the region.
8. A method according to Claim 7, wherein the part of the inner layer is machined away using a machine having a rotating milling head with a milling surface on an end face.
9. A method according to Claim 6, wherein the part of the inner layer is removed by cutting away the part from the remainder of the inner layer and pulling it out of the tube.
10. A method according to Claim 9, wherein the part of the inner layer is cut away using a machine having a rotating spindle carrying a radially-extending knife blade.
11. A method according to Claim 9 or 10, wherein the tube has an interlayer between the inner and outer layers preventing bonding between the inner and outer layers.
12. A method according to Claim 11, wherein the interlayer is of polyethylene.
13. A method according to any one of Claims 6 to 12, wherein the inner layer is of a stiffer material than the outer layer.
14. A method according to any one of Claims 6 to 13, wherein the outer layer is end formed after removal of the part of the inner layer to close the one end of the tube, and wherein a side opening is formed in the tube towards the one end.

15. A catheter substantially as hereinbefore described with reference to the accompanying drawing.
16. A method of making a medico-surgical tube according to any one of Claims 1 to 5 or Claim 15.
17. A method of making a catheter substantially as hereinbefore described with reference to Figures 1 to 4 of the accompanying drawing.
18. A method of making a catheter substantially as hereinbefore described with reference to Figures 1 to 4 as modified by Figures 5 and 6 of the accompanying drawing.
19. A medico-surgical tube made by a method according to any one of Claims 6 to 14, 17 or 18.
20. A machine for use in a method according to any one of Claims 6 to 14, 17 or 18.
21. A machine substantially as hereinbefore described according to Figures 1 to 4 of the accompanying drawing.
22. A machine substantially as hereinbefore described according to Figures 1 to 4 as modified by Figures 5 and 6 of the accompanying drawing.

23. Any novel and inventive feature or combination of features as hereinbefore described.



Application No: GB 9909411.2
Claims searched: 1-19

Examiner: Dr Steve Chadwell
Date of search: 8 September 1999

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.Q): F2P (PC25, PC26, PC27, PC29, PM9)

Int Cl (Ed.6): A61M 25/00

Other: Online: WPI, EPODOC

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
X	EP 0597341 A1 (TARGET...) see whole document, especially figure 3	1,5,16
X	WO 94/01160 A1 (ARROW...) see whole document, especially figure 2	1,5,16
X	US 4775371 (ADVANCED...) see whole document, especially figures 5-7	1,5,16
X	US 4385635 (RUIZ) see whole document, especially figure 2	1,4,5,16

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.